TECHNICAL SPECIFICATION

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Respiratory protective devices — Selection, use and maintenance —

Part 4: Selection and usage guideline for respiratory protective devices under pandemic/epidemic/outbreak of infectious respiratory disease

Appareils de protection respiratoire — Choix, utilisation et entretien —

Partie 4: Choix et lignes directrices d'utilisation des appareils de protection respiratoire en cas de flambée/épidémie/pandémie de maladie respiratoire infectieuse

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94, *Personal safety — Personal protective equipment*, Subcommittee SC 15, *Respiratory protective devices*.

A list of all parts in the ISO 16975 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

National and international health organisations such as the World Health Organization (WHO) recommend respiratory protective devices (RPDs) and/or other forms of face coverings such as surgical masks and barrier masks as part of a strategy for the prevention and control of infection and to limit the spread of infectious respiratory diseases. Depending on the type, RPDs and other mask forms, like face coverings, can be used either for individual protection such as for healthcare workers or in the case of the general public to reduce infectious transmission, i.e. as source control.

This document contains information on risk assessment, on the selection of adequate and suitable RPD and provides essential guidance on its use, care and maintenance. This document details the requirements for adjusting or establishing and implementing a programme for the use of RPD during a pandemic/epidemic/outbreak of an infectious respiratory disease.

Infectious respiratory disease can be transmitted in several ways. Transmission modes can include:

a) “droplets”, which are relatively large airborne particles containing the pathogen;

b) “aerosols” or airborne transmission, which consists of smaller particles with effective transport over distance and longer residence time in the air;

c) “contact”, whereby the pathogen is transmitted to the nose, mouth or eyes via a contaminated surface.

Exposure via all routes to an infectious respiratory disease should be eliminated or effectively controlled and reduced to a minimum by the application of adequate protective measures. Aerosols and smaller droplets can be significant airborne inhalation hazards.

Due consideration of other occupational hygiene controls and infection prevention measures such as engineering and administrative controls like ventilation, social distancing, environmental cleaning and hand hygiene should be given in conjunction with the selection and deployment of RPD by way of a sufficient and suitable risk assessment.

The informative annexes provide an explanation of the difference in performance and purpose of RPD and their various national and jurisdictional standards, as well as an explanation of the role and uses of surgical/medical masks and face coverings (barrier masks).

Respiratory protective devices — Selection, use and maintenance —

Part 4: Selection and usage guideline for respiratory protective devices under pandemic/epidemic/outbreak of infectious respiratory disease

1 Scope

This document specifies detailed information to assist the responsible person to select, use and maintain respiratory protective devices (RPD) in the context of a pandemic/epidemic/outbreak of infectious respiratory disease at the workplace. This document is intended for workplace applications and to guide those developing pandemic-related respiratory protection programs.

The guidance contained in this document is not intended to be exhaustive but highlights important aspects to which attention is given. It is used in conjunction with ISO/TS 16975-1, ISO/TS 16975-2 and ISO 16975-3 for all workplaces, including healthcare.

This document focuses on particle filtering RPD only as respiratory protection against pathogens.

This document does not apply to RPD programmes for RPD used exclusively for medical life support respirators and resuscitators.

The information contained in this document can be used to assist in the preparation of national or local regulations and guidance; however, this document does not supersede national or local regulations and guidance.

This document is not applicable to non-workplace situations.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
aerosol
suspension of solid, liquid, or solid and liquid particles in a gaseous medium, having a negligible falling velocity (generally considered to be less than 0,25 m/s)

[SOURCE: ISO 16972:2020, 3.6]

3.2
airborne transmission
spread of an infectious disease through infectious particles that remain suspended in the air over long distances and time (as *aerosols*) (3.1)

Note 1 to entry: Infection can also be transmitted through the air by larger droplets that are carried by airflow to the breathing zone of other persons.

3.3
aerosol generating procedure
AGP
medical procedures that generate higher concentrations of infectious respiratory aerosols than coughing sneezing, talking or breathing

Note 1 to entry: These aerosol generating procedures (AGPs) potentially put healthcare personnel and others at an increased risk for pathogen exposure and infection. There is neither expert consensus, nor sufficient supporting data, to create a definitive and comprehensive list of AGPs for healthcare settings.

Commonly performed medical procedures that are often considered AGPs, or that can create controlled or uncontrolled respiratory secretions, include:

— open suctioning of airways;

— sputum induction;

— cardiopulmonary resuscitation;

— endotracheal intubation and extubation;

— non-invasive ventilation;

— bronchoscopy.

3.4
asymptomatic
not showing signs or symptoms of the associated disease

3.5
community face covering
barrier mask
barrier face covering
face covering
product worn on the face, covering at least the wearer's nose and mouth, with the primary purpose to reduce the release of *droplets* (3.6) and particulate matter from the wearer into the immediate environment

Note 1 to entry: These products are not classed as RPD.

3.6
droplet
very small drops of liquid such as a particle of moisture discharged from the mouth during coughing, sneezing, or speaking

3.7
droplet transmission
infection spread through exposure to respiratory *droplets* (3.6) exhaled by an infectious source

3.8
epidemic
increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area

3.9
extended use
use/reuse of a “single use” respirator product over multiple or longer periods than intended

3.10
fit test
use of a challenge agent and a specific protocol to qualitatively or quantitatively determine the effectiveness of the seal between the wearer's face and respiratory interface of a specific make, model and size of a *respiratory protective device* (3.18).

[SOURCE: ISO 16972:2020, 3.91]

3.11
general public
all individuals in society who are not conducting work activities

3.12
healthcare worker
HCW
healthcare professional involved in the direct provisions of healthcare

[SOURCE: ISO/TR 19231:2014, 3.11]

3.13
infectious respiratory disease
disease caused by a pathogen that is either transmitted via inhalation or contact with the nose or mouth or causes clinically significant pathologic changes in the respiratory tract

Note 1 to entry: They can be caused by viruses, bacteria, fungi or spores. Many, but not all, can be transmitted from human to human. For simplicity, the general term “pathogen” is used throughout this document.

3.14
outbreak
greater-than-anticipated increase in the number of endemic cases in an area. It can also be a single case in a new area

Note 1 to entry: If not quickly controlled, an outbreak can become an *epidemic* (3.8).

3.15
pandemic
epidemic (3.8) that has spread over several countries or continents, usually affecting a large number of people

3.16
pathogen
infectious micro-organism or agent, such as a virus, bacterium, protozoan, prion, viroid, or fungus that can cause disease

Note 1 to entry: See also *infectious respiratory disease* (3.13)

3.17
respiratory interface
RI
part of a respiratory protective device (RPD) that forms the protective barrier between the wearer’s respiratory tract and the ambient atmosphere

Note 1 to entry: The RI is connected to the filtering part of the RPD or the part managing the supply of breathable gas.

[SOURCE: ISO 16972:2020, 3.202]

3.18
respiratory protective device
RPD
personal protective equipment designed to protect the wearer's respiratory tract against the inhalation of hazardous atmospheres

[SOURCE: ISO 16972:2020, 3.203]

3.19
social distancing
practice of maintaining a greater than usual physical distance from other people or of avoiding direct contact with people or objects in public places during the *pandemic* (3.15)/*epidemic* (3.8)/*outbreak* (3.14) of an infectious disease to minimize exposure and reduce the transmission of infection

3.20
source control
intervention to reduce release of *aerosols* (3.1) and *droplets* (3.6) at or close to the point of origin or release into the atmosphere

3.21
surgical mask
medical mask
product that covers the wearer's nose and mouth and provides a physical barrier to fluids and particulate materials

Note 1 to entry: These products are not classed as RPD.

3.22
surgical respirator
tight fitting RPD designed and tested for respiratory protection performance for compliance with an applicable national standard e.g. rated as N95, FFP2, KN95 etc. as well as having performance for fluid resistance and other parameters

3.23
tight-fitting respiratory protective device
tight-fitting RPD
respiratory protective device (3.18) which forms a protective barrier between the wearer's respiratory tract and the ambient atmosphere by forming a seal to the wearer's skin

3.24
workplace
designated area or areas (static or mobile) in which the work activities are carried out

4 Situations recommending protection from airborne hazards

Infectious respiratory diseases can be transmitted through the air via respiratory exhaled or expelled droplets and aerosols, and through contact with contaminated surfaces. RPD, together with other occupational hygiene control measures can form part of the overall control strategy. Selection and deployment of RPD in a pandemic/epidemic/outbreak situation should be by way of a sufficient and suitable risk assessment and managed by an effective RPD programme based on ISO/TS 16975-1 and ISO/TS 16975-2 and this document.

The use of a device by persons who are potential sources of pathogens needs to be considered in addition to ventilation control and other measures. Intention is to reduce the risk of transmitting or acquiring a respiratory infectious disease.

In some instances, the primary purpose is to prevent the individual from inhaling the pathogen (e.g. a HCW treating a patient), whereas in others, the primary purpose is to prevent an infected person from releasing the pathogen into the air, exposing others nearby. The devices used fall into several groups

including respiratory protective devices, surgical/medical masks, and face coverings (see Clause 3 for definitions). See Annex A for more information.

5 Situations for using RPD in the workplace

5.1 General

Under pandemic situations, additional risk assessments might be needed.

5.2 Healthcare

While there are situations in normal activities where a HCW may need to wear an RPD, in a pandemic/epidemic/outbreak situation this requirement can become much broader and many more HCWs will be required to wear a RPD routinely during their work shift. HCWs carrying out tasks with an identified risk should follow recommended national and local infection prevention and control procedures, including those associated specifically with the pandemic/epidemic/outbreak. These can include exposure control actions such as isolation, triaging, specialised air management, work practices (hygiene, respiratory etiquette strategies, distancing, administration actions, etc.) and use of RPD or other protective products to reduce the risk of infection.

5.3 Other workplaces

Each workplace shall be assessed appropriately using the latest pandemic/epidemic/outbreak related information available from the health authorities to determine the appropriate RPD or protection needed (if any).

NOTE For guidance on the implementation and use of RPD for the control of exposure to existing workplace hazardous substances see ISO/TS 16975-1. This is an exposure issue that is independent of a pandemic/epidemic/outbreak situation.

Some workplaces may already be using RPD for their work activities. Following a new risk assessment these may also provide them a suitable level of protection from airborne infectious particulates in a pandemic/epidemic/outbreak.

Other workplaces may not normally need RPD, but an additional risk assessment may indicate this step has become necessary to protect the wearer in a pandemic/epidemic/outbreak situation.

Where RPD is also recommended as part of the overall control strategy, the level of protection required or recommended with respect to the types and classes of RPD is often provided by national and international health organisations. The correct selection, use, care and maintenance of the recommended types and classes of RPD is vital to achieve effective protection from this RPD. (See ISO/TS 16975-1 and this document).

Other workplaces may not have any specific extra exposure issues in their activities and should follow the recommendations of the relevant health authorities regarding the need for use of other products such as surgical masks and face coverings as well as other controls like social distancing, cough/sneeze etiquette, etc. See Annex A and Annex C for further information.

6 RPD types and classes

ISO/TS 16975-1:2016, Annex A and Annex H, provide information on RPD types and classes, some of which can be suitable for use during an infectious respiratory disease pandemic/epidemic/outbreak.

Annex B also provides some additional information on current RPD types and classes across different countries/regions.

NOTE Some countries have a national system for assessment/approval/clearance of RPD of various types and all medical devices including surgical masks". Some jurisdictions also require or promote independent certification by a government or independent auditing body to certify the product is made to a certain standard or performance.

7 National (country wide) respiratory protective guidelines/program under a pandemic/epidemic/outbreak of respiratory disease

7.1 General

In a pandemic/epidemic/outbreak (as declared by the relevant health authority), there can be guidance and controls described by a Government or relevant authority to limit the transmission of the disease, including the use of respiratory protection devices and other protective products. The general elements of an RPD programme are described in ISO/TS 16975-1. This document provides information on the extra considerations and decisions that shall be made in a pandemic/epidemic/outbreak regarding some of the elements of the programme.

7.2 Employer responsibility

7.2.1 General

The employer must follow the Government's or relevant health authority's guidelines and directions in respect of protecting their employees at work. The use of RPD for prevention of transmission of infectious disease shall be supported by a respiratory protection programme as described in ISO/TS 16975-1.

During a pandemic/epidemic/outbreak, the employer's responsibility also includes control of potential infection in addition to control of exposure to any industrial inhalation hazard occurring from their work operations.

The employer can appoint an RPD/OSH administrator to be responsible for the operation of the entire RPD programme and provide adequate resources and organization to ensure the programme's continued effectiveness.

The employer and the programme administrator may be the same person.

7.2.2 RPD programme administrator

The programme administrator shall be responsible for effective management and regular review of the entire RPD programme.

7.3 Public place service provider responsibility

Any service provider or employer located in public places must follow the current Government or relevant authority guidelines in respect of protecting their employees (and the general public) during a pandemic/epidemic/outbreak.

7.4 RPD wearer (general)

The RPD wearer shall be responsible for proper use of their RPD – see ISO/TS 16975-1:2016, 6.3.4, for detail. In a pandemic/epidemic/outbreak situation, there may be extra procedures and controls required and changes to manufacturer's instructions that also shall be followed by all RPD wearers.

7.5 RPD manufacturers' responsibilities

As a pandemic/epidemic/outbreak evolves, provisional or new governmental requirements which are essential for the manufacturer to follow may be published. These new requirements can contain but are not limited to the following aspects:

— provisional changes in requirements on testing, certification and approval;

— additional information to be provided by the manufacturer regarding selection, use (donning, doffing, fitting), cleaning, disinfection, reuse and disposal of the product under a pandemic/epidemic/outbreak context;

— additional record keeping requirement for traceability purposes of the product.

The manufacturer is also responsible for monitoring expiration of any temporary requirements and to stop these when specified.

8 RPD programme

8.1 General

The RPD programme includes processes for selecting, using and maintaining RPD to ensure adequate protection to the wearer. This is described in detail in ISO/TS 16975-1. A pandemic/epidemic/outbreak would additionally involve activities to minimise the risk of infection transmission in activities supporting the deployment of RPD.

Prior to using RPD, it is essential to establish a written RPD programme. The RPD programme needs to be understood by all persons within the organization, as appropriate.

The required elements of a RPD programme as given in ISO/TS 16975-1:2016, 6.2, are:

— roles and responsibilities;

— RPD programme implementation;

— risk assessment;

— selection procedures;

— medical assessment;

— respirator fit testing;

— training;

— use of respirators;

— maintenance procedures including cleaning;

— storage;

— programme evaluation and review;

— records and record keeping.

8.2 Roles and responsibilities

See ISO/TS 16975-1:2016, 6.3, and 7.2 to 7.4 in this document for specifics associated with various roles and responsibilities.

8.3 RPD programme implementation

The RPD programme shall be implemented, evaluated and updated as necessary to reflect those changes in workplace conditions relative to the pandemic/epidemic/outbreak that affect RPD use.

The RPD programme should also include plans and actions to consider in the event of pandemics/epidemics/outbreaks as part of work plans.

8.4 Risk assessment

General risk assessment and selection information is found in ISO/TS 16975-1:2016, 7.1.

In a pandemic/epidemic/outbreak, the relevant risk assessment information should be sought from the government or relevant health organisations to provide guidance and detail of the hazards and the practices and arrangements needed to control the spread and impact of the disease. Additionally, local, national or international health authorities are expected to recommend the types and classes of RPD to be used in various situations. Note that knowledge of the effects of factors including the following will increase as the pandemic/epidemic/outbreak progresses and therefore procedural and equipment changes may need to be made:

— transmission pathway(s) and community incidence;

— susceptibility of specific groups;

— transmission rate and variability;

— required disinfection processes;

— effective personal protective equipment (PPE);

— service life of RPD and filters.

This can, for example, require use of higher performing RPD to increase the protection of the wearer for certain high-risk tasks. The broadband protection afforded by RPD in reducing exposure to aerosols, which may include pathogens, shall be balanced with other healthcare specific provisions like barriers against blood penetration, biocidal properties or anti-viral properties as well as requirements on limiting physiological strain.

8.5 RPD selection

General selection information is found in ISO/TS 16975-1:2016, 7.2 and 7.3.

For workplaces in a pandemic/epidemic/outbreak situation, follow the current local, national or international guidance regarding information and detail of the recommended RPD. The RPD recommendation will most likely specify the types and classes of RPD according to local or national classifications, e.g. N95, PFF2 or FFP2 filtering facepiece, but it is the responsibility of the employer to ensure that the RPD provided to workers is both adequate against the hazard and suitable for the intended wearer and the task to be performed. Aerosol generating procedures (AGPs) in healthcare applications, may give rise to a greater risk of infectious transmission and may require an optimised balance between a high-level aerosol protection, high breathability to limit physiological strain, resistance to blood penetration and pathogen suppressing measures like biocidal or anti-viral surface treatments."

Use of RPD outside the workplace should follow recommendations of public health and other authorities. Use of RPD outside workplace situations needs special consideration due to non-existing structures to perform risk assessments.

RPD selection should consider the recommended types and classes of RPD and conduct a suitability assessment for both task and wearer. ISO/TS 16975-1 provides the essential basic steps in the suitability

assessment. Additional consideration in the suitability assessment relating to suitability within a pandemic/epidemic/outbreak of infectious respiratory disease are detailed below:

— duration of use – reuse or extended use options;

— ease of cleaning and decontamination;

— storage;

— compatibility with other PPE;

— compatibility with other essential (non-PPE) items of equipment for the task (e.g. eye lenses);

— use of RPD with exhalation valves (see A.2);

— continuity of RPD supply;

— availability of fit testing for tight-fitting facepieces;

— training/monitoring capability.

8.6 Medical assessment

Medical assessment is discussed in ISO/TS 16975-1:2016, 7.3.3.2 and D.2.1.

Assessment of RPD users should follow community standards and relevant regulations.

Seek medical advice to ensure that all relevant workers are medically fit to wear the selected RPD.

Medical assessment, which can vary from review via a simple questionnaire to an in-depth examination, can consider the following.

— Is the relevant RPD likely to lead to significant adverse effects for the individual?

— Does the potential wearer have any personal susceptibilities requiring a greater degree of protection?

— Is the user capable of carrying out work or other activities while using the selected device?

8.7 RPD fit testing

Any user of tight-fitting respiratory protective device shall be fit tested for each different make, model and size of facepiece used to determine the effectiveness of the seal between the wearer's face and the respiratory interface (RI), using the methodologies given in ISO 16975-3. In a pandemic/epidemic/outbreak when using tight-fitting RPD, specific consideration should be given to the issues of infection control procedures and disinfection processes of the testing equipment to prevent any cross contamination between fit test subjects and/or the fit tester. This approach can vary depending on the fit testing methodology selected.

In a pandemic/epidemic/outbreak, recommended fit testing resources may be temporarily unavailable. These situations include limited availability of qualified fit testing personnel and equipment, or inadequate protection measures available for personnel performing fit testing procedures.

Refer to national or local authorities for guidance in these situations.

8.8 Training

Users of RPD shall be trained as described in ISO/TS 16975-1:2016, 7.5. Use, inspection, assembly, donning and pre-use checks of the RPD should be addressed and be in accordance with the information provided by the manufacturer.

In a pandemic/epidemic/outbreak situation, further training pertaining to the use of the RPD can also be required and can include the following.

— Infection prevention and control procedures.

— RPD donning and doffing procedures taking into consideration other PPE required to be worn (PPE ensemble).

— Reuse and extended use of single shift RPD.

— RPD cleaning and disinfecting procedures appropriate to the specific pathogen. These may need to be determined with assistance from infection control experts and in consultation with manufacturers regarding suitable cleaning and infection control products and conditions.

— Disposal – measures available to collect and dispose of used RPD and associated materials effectively and safely.

8.9 Use of RPD

Use of RPD in general is covered in ISO/TS 16975-1:2016, 7.6.

In a pandemic/epidemic/outbreak, specific attention should be paid to prevention of cross contamination of RPD through appropriate donning and doffing procedures and to the cleaning, handling and disposal processes of used equipment.

WARNING — Regarding multiple devices covering the mouth and nose (e.g. double masking)

— It is important to note that the wearing of a surgical mask or community face covering over an RPD, is a practice not recommended by RPD manufacturers nor by health and safety regulators; it should also be noted that the wearing of a surgical mask or community face covering over an item of RPD is not consistent with the performance testing conditions against which the RPD was approved or certified.

— It is also important to state that the effect of wearing a community face covering over an item of RPD can have a detrimental effect on the fit, filtration and comfort resulting in an overall reduction of wearer protection.

— Always use any RPD in accordance with the manufacturer's instructions.

8.10 Maintenance procedures including cleaning

RPD maintenance should be carried out as described in ISO/TS 16975-1:2016, 7.7 and Annex F. Additionally, all specified pandemic/epidemic/outbreak related resources e.g., appropriate cleaning/disinfection processes, products, equipment and facilities should be available and understood by those involved to allow effective infection prevention and control and cleaning/disinfection processes to be carried out as required.

A suitable supply of RPD, spare parts, cleaning and disinfection supplies etc., and specified cleaning procedures to manufacturer's guidelines and facilities should be available to prevent cross contamination or infection. The implemented disinfection process shall not degrade the components and be checked to ensure there is no loss of protection after treatment. RPD after disinfection shall not constitute a hazard or nuisance for the wearer.

Arrangements shall be made for safe handling and disposal of contaminated RPD or relevant components that cannot safely be decontaminated. Relevant national or local procedures shall be followed.

8.11 Storage

RPD storage should be carried out as described in ISO/TS 16975-1:2016, 7.8 and according to the information supplied by the manufacturer

8.12 Programme evaluation and review

The RPD programme should be reviewed as detailed in ISO/TS 16975-1:2016, 7.9 and Annex G.

Particular attention should be paid to the pandemic/epidemic/outbreak control aspects associated with the respiratory protection programme elements as described throughout Clause 8.

8.13 Records and record keeping

RPD storage should be carried out as described in ISO/TS 16975-1:2016, 7.10.

Any changes or updated procedures introduced that are specific to the pandemic/epidemic/outbreak situation should be recorded and kept for reference.

Annex A
(informative)

The role and purpose of respiratory protective devices, surgical masks and community face coverings

A.1 General

In pandemic/epidemic/outbreak conditions respiratory protective devices (RPD), surgical masks and community face coverings can serve an important role in reducing the airborne (also hand to face) transmission of pathogens. It is important to understand the difference between RPD, surgical masks and community face coverings especially in terms of their purpose for use. See Table A.1 for comparison of different countries/regions facemask purpose of use.

Respiratory protective devices (RPD) are designed and tested for their ability to reduce the wearer's inhalation of hazardous substances. Hazardous substances include industry airborne hazards such as dust, gases and vapours, and micro-organisms such as respiratory infectious bacteria, viruses and/or other pathogens. RPD (without exhalation valves) may also be used to protect both the wearer and the environment, to reduce droplet transmission such as in nonsurgical operation health care areas.

Medical aerosol generating procedures (AGPs) create an aerosol transmission risk and can therefore require the use of suitable RPD. Please refer to your country/region's regulations for proper selection and use. Implementation of RPD requires a comprehensive supporting program (see ISO/TS 16975-1) and depending upon the RPD design, fit testing may be needed as part of the selection process (see ISO 16975-3)

For the general public users who are advised to use specified rated RPD, it is important to follow all instructions for use given by the authorities and by the manufacturer, including supplied fitting instructions.

Surgical masks (or medical masks) conforming to recognized standards are intended to be used in operating rooms and some health care settings and are designed to protect the patient and surgical working environment by preventing release of expelled/exhaled droplets from the wearer.

Non-fluid resistant surgical masks are intended to reduce both the wearer's exposure to droplets, and the transmission of expelled/exhaled droplets from the wearer to the surrounding environment. They are not rated as suitable for spray or projected fluid exposures. Some surgical masks (or medical face masks) are designed with additional fluid splash resistance capability to prevent certain level of pressured body fluid penetration and thus reduce the infection risk e.g., for some surgical operations or wound treatment.

WARNING — Refer to your country/region's regulations for proper selection information.

Face coverings (self-made or commercial face coverings made of cloth, other textiles, or paper) are intended to reduce the transmission of droplets from the wearer to the immediate environment. Another function of these devices is that they can prevent a certain level of contact between the hand and the nose/mouth, reducing the risk of infection due to a hand hygiene failure.

A.2 Exhalation valves

In addition to providing protection to the wearer, RPD may also serve as source control. As a source control, the RPD should reduce the release of potentially infectious particles to the immediate environment. Many filtering facepiece and elastomeric respirators have unfiltered exhalation valves,

permitting the user's exhaled air to bypass filtering as it is released to the surrounding air. In a similar manner, most Powered Air Purifying Respirators do not filter the exhaust air escaping from the headtop.

Advice of public health agencies and manufacturers should be followed regarding selection of valved RPD. A hazard assessment should be performed considering the conditions of use and the likelihood that a wearer will have an infection that is transmissible.

WARNING — Refer to your country/region's regulations for proper selection information.

Table A.1 — Comparison of different countries/regions non-RPD face coverings - purpose of use

Official Name	Country/ Region	Standard	Intended use			
			Protect others (prevent droplets release out)	Protect wearer from droplets	Protect wearer from airborne pathogens	Protect wearer from blood splash/penetration
Single-use medical face mask	China	YY/T0969-2013	Yes	Yes	No	No
Surgical mask	China	YY0469-2011	Yes	Yes	No	Yes
Medical face mask (Type I)	Europe	EN 14683:2019	Yes	Yes	No	No
Medical face mask (Type II)	Europe	EN 14683:2019	Yes	Yes	No	No
Medical face mask (Type IIR)	Europe	EN 14683:2019	Yes	Yes	No	Yes
Community face covering	Europe	CWA 17553	Yes	No	No	No
Single-use face mask (Level 1 barrier)	Australia/ New Zealand	AS 4381:2015	Yes	Yes	No	Yes
Single-use face mask (Level 2 barrier)	Australia/ New Zealand	AS 4381:2015	Yes	Yes	No	Yes
Single-use face mask (Level 3 barrier)	Australia/ New Zealand	AS 4381:2015	Yes	Yes	No	Yes
Medical face mask (Level 1 barrier)	USA	ASTM F2100-21	Yes	Yes	No	Yes
Medical face mask (Level 2 barrier)	USA	ASTM F2100-21	Yes	Yes	No	Yes
Medical face mask (Level 3 barrier)	USA	ASTM F2100-21	Yes	Yes	No	Yes
Barrier face coverings	USA	ASTM F3502-21	Yes	No	No	No
Surgical mask	Republic of Korea	MFDS 2020-36	Yes	Yes	No	Yes

Table A.1 *(continued)*

Official Name	Country/ Region	Standard	Intended use			
			Protect others (prevent droplets release out)	Protect wearer from droplets	Protect wearer from airborne pathogens	Protect wearer from blood splash/penetration
KF-AD (Korea Filter for Anti-droplet masks)	Republic of Korea	MFDS 2020-36	Yes	Yes	No	No

Annex B
(informative)

Comparison of different types and performance of particle filtering RPD across different International Standards

B.1 Overview

B.1.1 General

Users seeking information on the classification of RPD should refer to ISO 16973, which classifies RPD based on performance. The basic classification, which applies to all RPD, is given in the following order as specified in ISO 16973:

a) protection class;

b) work rate class;

c) respiratory interface class.

During a pandemic/epidemic/outbreak of infectious respiratory disease, where ISO classified products are not available, various types of Respiratory Protective Devices (RPDs) conforming with national or regional standards are utilised to reduce personal exposure to potential risks. Authorities often reference these standards when making respirator recommendations. It can become important to understand the similarities and differences of products conforming with standards from other countries or regions.

This annex provides a comparison of the global landscape of particle filtering RPD showing the different, but similar, performance characteristics of devices from various countries/regions.

Particle filtering respiratory protective devices includes non-powered particle filtering RPD and powered particle filtering RPD.

B.1.2 Non-powered particle filtering RPD

Table B.1 lists some national/regional standards which specify technical requirements for non-powered particle filtering RPD. During recent pandemics including COVID-19 and its variants, airborne transmission of pathogen via aerosols has become acutely more prominent."

Surgical respirators (or medical respirators) are filtering facepiece RPD with added fluid splash resistance, equivalent to surgical masks. Surgical respirators can reduce the wearer's exposure to aerosols and droplets, prevent exposure to blood and body fluids and significantly reduce the wearer's infection risk.

Table B.1 — National/regional standards for non-powered filtering facepiece RPD

Country/ Region	Publisher	Reference number of the standard	Description
ISO	ISO	ISO 17420-1:2021	Respiratory protective devices — Performance requirements — Part 1: General
		ISO 17420-2:2021	Respiratory protective devices — Performance requirements — Part 2: Requirements for filtering RPD

Table B.1 *(continued)*

Country/ Region	Publisher	Reference number of the standard	Description
Australia/ New Zealand	Australia/New Zealand Standards (AS/NZS)	AS/NZS 1716-2012	Respiratory protective devices Section 4 for particulate filter respirators
Brazil	Brazilian Association of Technical Standards (ABNT)	ABNT NBR 13698 :2011	Respiratory protective devices —Filtering half mask to protect against particles
		ABNT NBR 13694:2021 or ABNT NBR 13695:1996 together with ABNT NBR 13697:2010	Respiratory protective devices — Half masks and quarter masks or Respiratory protective equipment - Full face piece together with Respiratory protective devices — Particle filters
Canada	Canadian Standards Association (CSA)	CSA Z94.4.1	Performance of filtering respirators.
China	Standardization Administration of China (SAC)	GB 2626-2006/2019	Respiratory protection — Non-powered air-purifying particle respirator
European Union	European Committee for Standardization (CEN)	EN 149:2001+A1:2009	Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking
		EN 1827:1999+A1:2009	Respiratory protective devices – Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only – Requirements, testing, marking.
		EN 140:1998 or EN 136:1998 together with EN 143	Respiratory protective devices — Half masks and quarter masks — Requirements, testing and marking or Respiratory protective devices — Full face masks — Requirements, testing, marking together with Respiratory protective devices – Particle filters – Requirements, testing, marking
Japan	Japan Ministry of Health, Labour and Welfare (JMHLW)	JMHLW Notification 214, 2018	Standard for Dust Mask
Korea	Korean Ministry of Employment and Labour (KMOEL)	KMOEL Notification-2020-35	Ministry of Employment and Labour Notification No. 2020-35 Safety certification notice for protective equipment (*4-Dust mask)
Mexico	Norma Oficial Mexicana (NOM)	NOM-116-STPS-2009	Safety — Personal protective equipment— Anti-noxious particulate negative pressure air purifying respirators — Specifications and test methods

Table B.1 *(continued)*

Country/ Region	Publisher	Reference number of the standard	Description
Russian & Eurasian Economic Union	Euro-Asian council for Standardization, Metrology and Certification (EASC)	GOST 12.4.294-2015	Occupational safety standards system. Respiratory protective devices. Filtering half masks to protect against particles. General specifications.
		GOST 12.4.244-2013 or GOST 12.4.293-2015 together with GOST 12.4.246-2016	Occupational safety standards system. Respiratory protective devices. Half masks and quarter masks. General specifications or occupational safety standards system. Respiratory system protective devices. Masks. General specifications together with Occupational safety standards system. Respiratory protective equipment. Particle filters. General specifications
United States	U.S. National Institute for Occupational Safety & Health (NIOSH)	42 CFR Part 84 (10-1-19 Edition)	Approval of respiratory protective devices Subpart K —Air purifying particulate respirators

Table B.2 to Table B.4 shows comparison of national/regional standards for non-powered filtering RPD.

Table B.2 — Comparison of national/regional standards for non-powered particle filtering RPD — Filter performance

Country/ Region	Class[a]		Performance requirement— Minimum filter efficiency	Test for oil atmosphere[b]	Flow rate l/min
ISO	F1		80 %	Yes - All types	According to work rate class W1: 85 W2: 135 W3: 205 W4: 225
	F2		95 %		
	F3		99 %		
	F4		99,9 %		
	F5		99,99 %		
Australia/New Zealand	Both disposable and reusable	P1	80 %	No - All types	95
		P2	94 %		
		P3[c]	99,95 %		
Brazil	Disposable	PFF1S/PFF1SL	80 %	Yes - SL types No - S types	95
		PFF2S/PFF2SL	94 %		
		PFF3S/PFF3SL	99 %		
	Reusable	P1S/P1SL	80 %		
		P2S/P2SL	94 %		
		P3S/P3SL	99 %		

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as “disposable” and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as “reusable”.

[b] Filter testing with solid aerosols is an option available to all RPD test standards specified and was therefore not listed separately.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.2 *(continued)*

Country/ Region	Class[a]		Performance requirement— Minimum filter efficiency	Test for oil atmosphere[b]	Flow rate l/min
Canada	CA-N95/CA-R95/CA-P95		95 %	Yes - R, P types No - N Type	85
	CA-N99/CA-R99/CA-P99		99 %		
	CA-N100/CA-R100/CA-P100		99,97 %		
China	Both disposable and reusable	KN90/KP90	90 %	Yes - KP types No - KN types	85
		KN95/KP95	95 %		
		KN100/KP100	99,97 %		
European Union	EN 149:2001 +A1:2009	FFP1	80 %	Yes - All types	95
		FFP2	94 %		
		FFP3	99 %		
	EN 1827:1999 +A1:2009	FM P1 NR	80 %	Yes - All types	95
		FM P2 NR	94 %		
		FM P3 NR	99,95 %		
	EN 140:1998 or EN 136:1998 together with EN 143:2021	P1	80 %	Yes - All types	95
		P2	94 %		
		P3	99,95 %		
Japan	Disposable	DS1/DL1	80 %	Yes - DL types No - DS types	85
		DS2/DL2	95 %		
		DS3/DL3	99,9 %		
	Reusable	RS1/RL1	80 %	Yes - RL types No - RS types	85
		RS2/RL2	95 %		
		RS3/RL3	99,9 %		
Korea	Non-detachable	2nd Class	80 %	Yes - All types	95
		1st Class	94 %		
		Special class	99 %		
	Detachable	2nd Class	80 %	Yes - All types	95
		1st Class	94 %		
		Special class	99,95 %		
Mexico	Both disposable and reusable	N90/R90/P90	90 %	Yes - P/R types No - N types	85
		N95/ R95/P95	95 %		
		N100/ R100/ P100	99,97 %		
Russian & Eurasian Economic Union	Disposable	FFP1	80 %	Yes - All types	95
		FFP2	94 %		
		FFP3	99 %		
	Reusable	P1	80 %	Yes - All types	95
		P2	94 %		
		P3	99,95 %		

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as “disposable” and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as “reusable”.

[b] Filter testing with solid aerosols is an option available to all RPD test standards specified and was therefore not listed separately.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.2 *(continued)*

Country/ Region	Class[a]		Performance requirement— Minimum filter efficiency	Test for oil atmosphere[b]	Flow rate l/min
United States	Both disposable and reusable	N95/R95/P95	95 %	Yes - P/R types No - N types	85
		N99/ R99/P99	99 %		
		N100/ R100/ P100	99,97 %		

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] Filter testing with solid aerosols is an option available to all RPD test standards specified and was therefore not listed separately.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.3 — Comparison of national/regional standards for non-powered particle filtering RPD — Inhalation and exhalation resistance

Country/ Region	Class[a]		Performance requirement — Maximum allowed inhalation resistance		Performance requirement —Maximum allowed exhalation resistance	
			Pressure (hPa)	Flow rate (l/min)	Pressure (hPa)	Flow rate (l/min)
ISO[b]	All particle filter efficiency classes		-12,00[b]	10 35 65 105	12,00	10 35 65 105
			-20,00[b]	135	20,00	135
Australia/ New Zealand	Both disposable and reusable	P1	1,10	30	Half facepiece: 1,20	85
			3,40	95	Full face piece: 2,00	
		P2	1,20	30	Half facepiece: 1,20	
			3,70	95	Full face piece: 2,00	
		P3[c]	1,70	30	X[c]	
			5,70	95	Full face piece: 2,00	

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] ISO 17420-2:2021, Table 3, specifies requirements for work of breathing and elastance in addition to breathing resistance. Inhalation resistance is expressed by peak pressure, hence the negative value.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.3 *(continued)*

Country/ Region	Class[a]		Performance requirement — Maximum allowed inhalation resistance		Performance requirement —Maximum allowed exhalation resistance	
			Pressure (hPa)	Flow rate (l/min)	Pressure (hPa)	Flow rate (l/min)
Brazil	Disposable	PFF1S/PFF1SL	0,60	30	3,00	160
			2,10	95		
		PFF2S/PFF2SL	0,70	30		
			2,40	95		
		PFF3S/PFF3SL	1,00	30		
			3,00	95		
	Reusable	P1S/P1SL	0,60	30	3,00	160
			2,10	95		
		P2S/P2SL	0,70	30		
			2,40	95		
		P3S/P3SL	1,00	30		
			3,00	95		
Canada	CA-N95/-100 Pa CA-N95F-100 Pa		1	85	1	85
	CA-N95/-175 Pa CA-N95F-175 Pa		1,75		1,75	
	CA-N95/-343 Pa CA-N95F-343 Pa		3,43		2,45	
	CA-R95/CA-P95		3,43		2,45	
	CA-N99/N99F/R99/P99		3,43		2,45	
	CA-N100/N100F/R100/P100		3,43		2,45	
China	Disposable	KN90/KP90	1,70(valveless)/ 2,10(valved)	85	1,70 (valveless)/ 1,50(valved)	85
	Reusable		2,50		1,50	
	Disposable	KN95/KP95	2,10 (valveless)/ 2,50 (valved)		2,10 (valveless)/ 1,50 (valved)	
	Reusable		3,00		1,50	
	Disposable	KN100/KP100	2,50 (valveless)/ 3,00 (valved)		2,50 (valveless)/ 1,50 (valved)	
	Reusable		3,50		1,50	

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] ISO 17420-2:2021, Table 3, specifies requirements for work of breathing and elastance in addition to breathing resistance. Inhalation resistance is expressed by peak pressure, hence the negative value.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.3 *(continued)*

Country/ Region	Class[a]		Performance requirement — Maximum allowed inhalation resistance		Performance requirement —Maximum allowed exhalation resistance	
			Pressure (hPa)	Flow rate (l/min)	Pressure (hPa)	Flow rate (l/min)
European Union	EN 149:2001 +A1:2009	FFP1	0,6	30	3,00	160
			2,1	95		
		FFP2	0,7	30		
			2,4	95		
		FFP3	1,0	30		
			3,0	95		
	EN 1827:1999 +A1:2009	FM P1 NR	0,6	30	3,00	160
			2,1	95		
		FM P2 NR	0,7	30		
			2,4	95		
		FM P3 NR	1,2	30		
			4,2	95		
	EN 140:1998 or EN 136: 1998 together with EN 143:2021	P1	0,6	30	3,00	160
			2,1	95		
		P2	0,7	30		
			2,4	95		
		P3	1,2	30		
			4,2	95		
Japan	Disposable	DS1/DL1	0,60 (valved)/ 0,45 (valveless)	40	0,60 (valved)/ 0,45 (valveless)	40
		DS2/DL2	0,70 (valved)/ 0,50 (valveless)		0,70 (valved)/ 0,50 (valveless)	
		DS3/DL3	1,50 (valved)/ 1,00 (valveless)		0,80 (valved)/ 1,00 (valveless)	
	Reusable	RL1/RS1	0,70	40	0,70	40
		RL2/RS2	0,70		0,70	
		RL3/RS3	1,60		0,80	

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] ISO 17420-2:2021, Table 3, specifies requirements for work of breathing and elastance in addition to breathing resistance. Inhalation resistance is expressed by peak pressure, hence the negative value.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.3 *(continued)*

Country/ Region	Class[a]		Performance requirement — Maximum allowed inhalation resistance		Performance requirement —Maximum allowed exhalation resistance	
			Pressure (hPa)	Flow rate (l/min)	Pressure (hPa)	Flow rate (l/min)
Korea	Non-detachable	2nd Class	0,60	30	3,00	160
			2,10	95		
		1st Class	0,70	30		
			2,40	95		
		Special class	1,00	30		
			3,00	95		
	Detachable	Full facepiece	2,50	160	3,00	160
			0,50	30		
			1,50	95		
		Half facepiece	2,00	160		
			0,50	30		
			1,30	95		
Mexico	Both disposable and reusable	N90/R90/P90	3,43	85	2,45	85
		N90/ R95/P95				
		N100/ R100/ P100				
Russian & Eurasian Economic Union	Disposable	FFP1	0,60	30	3,00	160
			2,10	95		
		FFP2	0,70	30		
			2,40	95		
		FFP3	1,00	30		
			3,00	95		
	Reusable	P1	0,60	30	3,00	160
			2,10	95		
		P2	0,70	30		
			2,40	95		
		P3	1,00	30		
			3,00	95		
United States	Both disposable and reusable	N95/R95/P95	3,43	85	2,45	85
		N99/ R99/P99				
		N100/ R100/ P100				

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] ISO 17420-2:2021, Table 3, specifies requirements for work of breathing and elastance in addition to breathing resistance. Inhalation resistance is expressed by peak pressure, hence the negative value.

[c] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

Table B.4 — Comparison of national/regional standards for non-powered particle filtering RPD — Total inward leakage, inward leakage or fit performance

Country/ Region	Class[a]		Maximum allowed total inward leakage	
ISO	PC1		Second largest result TILMAX≤20 %	
	PC2		Second largest result TIL_{MAX} ≤5 %	
	PC3		Second largest result TIL_{MAX} ≤1 %	
	PC4		Second largest result TIL_{MAX} ≤0,1 %	
	PC5		Second largest result TIL_{MAX} ≤0,01 %	
	PC6		Second largest result TIL_{MAX} ≤0,001 %	
Australia/ New Zealand	Both disposable and reusable	P1	Mean TIL value of 50 results ≤22 %	All TIL values of 50 results ≤22 %
		P2	Mean TIL value of 50 results ≤8 %	All TIL values of 50 results ≤8 %
	Reusable Full facepiece	P3[b]	Mean TIL value of 50 results ≤0,05 %	All TIL values of 50 results ≤0,05 %
Brazil	Disposable	PFF1S/PFF1 SL	Not specified	
		PFF2S/PFF2 SL		
		PFF3S/PFF3 SL		
	Reusable	P1S/P1SL	Not specified	
		P2S/P2SL		
		P3S/P3SL		
Canada	CA-N95-100 Pa, CA-N95-175 Pa, CA-N95-343 Pa, CA-N95F-100 Pa, CA-N95F-175 Pa, CA-N95F-343 Pa, CA-N99, CA-N99F, CA-N100, CA-N100F, CA-R95, CA-R99, CA-R100, CA-P95, CA-P99, CA-P100		Respirators, except for loose-fitting respirators shall meet quantitative fit test requirements with human subjects representing the range of facial dimensions found in the working population. at least 70 % of test subjects (total 25) shall obtain an overall fit factor greater than or equal to the minimum fit factor required for the respirator. Minimum fit factors shall be as follows: a) filtering facepiece and half-facepiece respirators: 100; and b) full-facepiece respirators: 500	
China	Disposable	KN90/KP90	At least 46 out of 50 individual results ≤13 %	At least 8 out of 10 individual wearer means ≤10 %
		KN95/KP95	At least 46 out of 50 individual results ≤11 %	At least 8 out of 10 individual wearer means ≤8 %
		KN100/KP100	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
	Reusable	Half facepiece	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
		Full facepiece	At least 46 out of 50 individual results ≤0,05 %	At least 8 out of 10 individual wearer means ≤0,05 %

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full-face mask and particulate filter.

[c] In Japan standard, inward leakage (IL) rather than total inward leakage (TIL).

[d] No requirement.

Table B.4 *(continued)*

Country/ Region	Class[a]		Maximum allowed total inward leakage	
European Union	EN 149:2001 +A1:2009	FFP1	At least 46 out of 50 individual results ≤25 %	At least 8 out of 10 individual wearer means ≤22 %
		FFP2	At least 46 out of 50 individual results ≤11 %	At least 8 out of 10 individual wearer means ≤8 %
		FFP3	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
	EN 1827:1999 +A1:2009 RPD without exhalation valve	FM P1 NR	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
		FM P2 NR		
		FM P3 NR		
European Union	EN 140:1998 together with EN 143:2021	P1	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
		P2		
		P3		
	EN 136:1998 together with EN 143:2021	P1	The inward leakage of the test agent shall not exceed an average value of 0,05 % of the inhaled air for any of the ten test subjects in any of the test exercises.	
		P2		
		P3		
Japan	Disposable	DS1/DL1	Inward leakage[c] rate is to be measured and included in user instructions for disposable type only.	
		DS2/DL2		
		DS3/DL3		
	Reusable	RL1/RS1	X[d]	
		RL2/RS2		
		RL3/RS3		
Korea	Non-detachable	2nd Class	≤25 %	
		1st Class	≤11 %	
		Special class	≤5 %	
	Detachable	Full facepiece	≤0,05 %	
		Half facepiece	≤5 %	
Mexico	Both disposable and reusable	N90/R90/P90	X[d]	
		N90/ R95/P95		
		N100/ R100/P100		

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full-face mask and particulate filter.

[c] In Japan standard, inward leakage (IL) rather than total inward leakage (TIL).

[d] No requirement.

Table B.4 *(continued)*

Country/ Region	Class[a]		Maximum allowed total inward leakage	
Russian and Eurasian Economic Union	Disposable	FFP1	At least 46 out of 50 individual results ≤25 %	At least 8 out of 10 individual wearer means ≤22 %
		FFP2	At least 46 out of 50 individual results ≤11 %	At least 8 out of 10 individual wearer means ≤8 %
		FFP3	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
	GOST 12.4.190-99 together with GOST 12.4.246-2016	P1	At least 46 out of 50 individual results ≤5 %	At least 8 out of 10 individual wearer means ≤2 %
		P2		
		P3		
	GOST 12.4.293-2015 together with GOST 12.4.246-2016	P1	The inward leakage of the test agent shall not exceed an average value of 0,05 % of the inhaled air for any of the ten test subjects in any of the test exercises.	
		P2		
		P3		
United States	Both disposable and reusable	N95/R95/P95	No total inward leakage requirement in this standard, other technical specifications included quantitative testing for TIL, and requirement of fit testing before use.	
		N99/ R99/P99		
		N100/ R100/P100		

[a] Products covered: filtering facepiece (RPD entirely or substantially constructed of filtering material) which is often referred to as "disposable" and RPD consisting of respiratory interface (e.g. half face mask, full face mask) and particle filter which is often referred to as "reusable".

[b] Specified in AS/NZS 1716-2012, half face masks are not allowed to indicate P3 level protection, hence no P3 FFRs. P3 level protection only allowed for RPD incorporating a full face mask and particulate filter.

[c] In Japan standard, inward leakage (IL) rather than total inward leakage (TIL).

[d] No requirement.

National and regional standards for powered particle filtering RPD are given in Table B.5 to B.8.

Table B.5 — National/regional standards for powered particle filtering RPD

Country/ Region	Publisher	Reference number of the standard	Description
ISO	ISO	ISO 17420-1:2021	Respiratory protective devices — Performance requirements — Part 1: General
		ISO 17420-2:2021	Respiratory protective devices — Performance requirements — Part 2: Requirements for filtering RPD
Australia/ New Zealand	Australia/New Zealand Standards (AS/NZS)	AS/NZS 1716-2012	Respiratory protective devices Section 6 for powered air-purifying respirators
China	Standardization Administration of China (SAC)	GB 30864-2014	Respiratory protection — Powered air-purifying respirator
European Union	European Committee for Standardization (CEN)	EN 12941:2022[a]	Respiratory protective devices — Powered filtering devices incorporating a loose fitting respiratory interface — Requirements, testing, marking
		EN 12942:2022[a]	Respiratory protective devices — Power filtering devices incorporating full face masks, half masks or quarter masks — Requirements, testing, marking

[a] Under publication

Table B.5 *(continued)*

Country/ Region	Publisher	Reference number of the standard	Description
Japan	Japan Ministry of Health, Labour and Welfare (JMHLW)	JMHLW Notification 455, 2014	Standard for powered air purifying respirator
Korea	Korean Ministry of Employment and Labour (KMOEL)	KMOEL Notification-2020-35b	Ministry of Employment and Labour Notification No. 2020-35 Safety certification notice for protective equipment (*7-Powered respirators)
Russian & Eurasian Economic Union	Euro-Asian Council for Standardization, Metrology and Certification (EASC)	GOST 12.4.234-2012	Occupational safety standards system. Respiratory protective devices. Powered filtering devices incorporating a helmet or a hood. Requirements, testing, marking
		GOST EN 12942-2012	Respiratory protective devices — Power assisted filtering devices incorporating full face masks, half masks or quarter masks — Requirements, testing, marking
United States	U.S. National Institute for Occupational Safety & Health (NIOSH)	42 CFR Part 84(10-1-19 Edition)	Approval of respiratory protective devices Subpart KK — Dust, Fume, and Mist; Pesticide; Paint Spray; Powered Air-Purifying High Efficiency Respirators and Combination Gas Masks

[a] Under publication

Table B.6 — Comparison of national/regional standards for powered particle filtering RPD — Filter performance

Country/Region	Class	Performance Requirement —Minimum filter efficiency	Test for oil atmosphere	Flow rate (l/min)
ISO	F1	80 %	Yes-all types	Test flow rate calculated from averaged maximum and minimum interactive flow rate
	F2	95 %		
	F3	99 %		
	F4	99,9 %		
	F5	99,99 %		
Australia/ New Zealand	PAPR-P1	95 %	No - All types	Test at flow rate of the respirator measured when fitted with a fully charged battery measured after 30 min running time
	PAPR-P2	99 %		
	PAPR-P3	99,95 %		
China	P95	95 %	Yes (oil particle test only)	Negative pressure PAPR: 85 l/min; Positive pressure PAPR with tight-fitting facepiece: peak interactive flow rate; Positive pressure PAPR with loose-fitting facepiece: actual flow rate obtained at state of MMDF
	P100	99,97 %		